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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,195	10/30/2003	Eric M. Leproust	10030416-1	3542

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AGILENT TECHNOLOGIES INC.
INTELLECTUAL PROPERTY ADMINISTRATION,LEGAL DEPT.
MS BLDG. E P.O. BOX 7599
LOVELAND, CO 80537

EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
08/21/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPOPS.LEGAL@agilent.com

Office Action Summary	Application No.	Applicant(s)	
	10/698,195	LEPROUST ET AL.	
	Examiner	Art Unit	
	JASON M. SIMS	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,13-15,22 and 24-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 13-15, 22, and 24-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 3/31/2008, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-10, 13-15, 22, and 24-31 are the current claims hereby under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10, 22, and 24-29 are drawn to a process. A statutory process must include a final resulting step of a physical transformation, or produce a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

> The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to 9 -- process, machine,

manufacture, or composition of matter–but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. *See In re Warmerdam*, 33 F.3d 1354, 1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 1-10, 22, and 24-29 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or to a user, or by including a final resulting step of a physical transformation, if such wording is supported by the instant specification.

Response to arguments:

Applicant's arguments, filed 3/31/2008, with respect to the rejection of claim 31 under 35 USC 101 have been fully considered and are persuasive

because of applicant's arguments. Therefore the rejection of claim 31 has been withdrawn.

Applicant's arguments filed 3/31/2008 with respect to the rejection of claims 1-10, 22, and 24-29 have been fully considered but they are not persuasive.

Applicant argues that case law suggest that a requirement such that results be output to a specific source in order to be tangible is misplace and therefore the instant rejection of claims under 35 USC 101 for being drawn to non-statutory subject matter is inappropriate.

Applicant's arguments are not found persuasive because it is the United States Patent and Trademark's official policy to determine patentable subject matter according to the interim guidelines. Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application. In the instant case it is unclear as to what is done with the resulting data, which may be seed data for another data manipulation program prior to being effectively communicated to an end user in the "real" world, i.e. outputted to a display or user, which produces a practical application.

Claim Rejections - 35 USC § 103-maintained

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 13-15, 22, 24-27, and 30-31 are rejected under 35 U.S.C. 103(a) as being obvious over McGall (US P/N 5,843,655) in view of Tomiuk et al. (December 2001).

The claims are directed to a method of identifying a sequence of a nucleic acid for use as a substrate surface immobilized probe for a target nucleic acid, said method comprising: (a) determining a full length synthesis probability measure for each member sequence of a set of a plurality of candidate probe sequences for said target nucleic acid by evaluation of the susceptibility to depurination during synthesis of each probe sequence; and (b) employing said determined full length synthesis probability measures to select a sequence for use as a substrate immobilized probe for said target nucleic acid.

McGall teaches limitations of claims 1-7, 13-15, 22, 24-27, and 30-31 at the abstract, col. 1, lines 5-51, col. 4, lines 12-36, col. 8, lines 50-67 and col. 9, lines 1-21. McGall teaches a method for identifying sequences for use as

substrate surface immobilized probes. McGall teaches testing many different sequences of candidate probes by determining susceptibility to depurination, using algorithms for comparing hybridization patterns, and using these determined values to select sequences for use as substrate surface immobilized probes. Furthermore, McGall at col. 4, teaches a method of testing as a screening and optimization process. Moreover, McGall at col. 4 and col. 8 – col. 9 discusses the use of various quality parameters for testing and screening such as an amount of deprotection of oligonucleotides and optimizing deprotection methods, which reads on a threshold parameter used for deblock doses. McGall at col. 8, lines 51-67, col. 9, and col. 10, lines 1-34 where it optimizing deprotection methods and susceptibility to depurination are discussed.

McGall does suggests but does not specifically teach selecting a sequence for use as a substrate. McGall suggests this limitation because a method of screening the sequences used reads on the broad interpretation of a selection process.

Tomiuk et al. teaches this limitation throughout the invention and in particular at the abstract, page 329, paragraph 1, page 330, first column, paragraph 1 and second column, paragraphs 1-2. Moreover, Tomiuk et al. discusses at page 329, column 1, paragraph 1 how a successful microarray application requires particular conditions and prerequisites for selecting appropriate DNA probes for an situ nucleic acid synthesis where the probe sequence is selected from a set of candidate sequences. Tomiuk et al. discusses, at the abstract, page 330, first column, paragraph 1 and second

column, paragraphs 1-2, probe selection strategies and the use of computer programs for the optimal choice of oligonucleotide sequence selection, which reads identifying a sequence of a nucleic acid for use as a substrate surface immobilized probe from a set of candidate probe sequences and determining a full length synthesis probability measure via an algorithm. Furthermore, Tomiuk et al. discusses the need to pay special attention to sequence characteristics such as, for example, composition and order of bases.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use some of the parameters measured in McGall for pre-selecting sequences for potential use a substrate immobilized probe because one would be motivated to further optimize manufacturing success.

Response to Arguments

Applicant's arguments filed 3/31/2008 have been fully considered but they are not persuasive.

Applicant's statement made under 103 (c) is acknowledged. However applicant's made this statement in order to disqualify the Minor et al. prior art reference.

Applicant's argument is not found persuasive because with regards to the instant rejection of claims 1-7, 13-15, 22, 24-27, and 30-31 being rejected under 35 U.S.C. 103(a) as being obvious over McGall (US P/N 5,843,655) in view of Tomiuk et al. (December 2001) and further in view of Minor et al. (Pub No. US 2004/0019466) it was clear from the Non-Final office action mailed out 12/31/2007 that the Minor et al. reference was not used in the rejection and was

inappropriately stated in the beginning paragraph. The rejection was clear with regards to its use of only McGall and Tomiuk references without any reliance on Minor et al. Therefore, the rejection is not being withdrawn because of applicant's statement under 103 (c).

Applicant further argues that nowhere does McGall teach or suggest determining a full length synthesis probability measure for probe sequences.

Applicant's argument is not found persuasive because the claimed invention recites a method of determining a full length synthesis probability measure by "determining the susceptibility to depurination during synthesis of each probe sequence." Therefore, applicant is arguing that McGall does not teach determining the susceptibility to depurination during synthesis of each probe sequence. McGall at col. 1, lines 30-34 teach using biological chips wherein arrays of probes are oligonucleotides are used to extract information from nucleic acid samples. In other words, McGall teaches arrays of oligonucleotide probes. McGall further teaches at col. 2, lines 48-61 determining the extent of depurination of oligonucleotides on a substrate during synthesis, wherein the oligonucleotides are probes, wherein determining the extent of depurination reads on determining the susceptibility to depurination. Therefore, McGall teaches determining the susceptibility to depurination during synthesis of each probe sequence, which is step (a) of claim 1. Furthermore, McGall at col. 4, lines 13-17, teaches a method of optimizing the production of arrays of probes based on the above testing methods. Therefore, McGall teaches employing the

values of the extent of depurination of oligonucleotides on a substrate during synthesis to optimize the production of the oligonucleotides on the arrays.

Applicant argues that Tomiuk et al. does not teach determining a full length synthesis probability measure for probe sequences and selection.

Applicant's argument is not found persuasive because the Tomiuk et al. reference was used to teach the limitation of selecting a particular sequence for use as a substrate immobilized probe. Tomiuk et al. discusses at page 329, column 1, paragraph 1 how a successful microarray application requires particular conditions and prerequisites for selecting appropriate DNA probes for an situ nucleic acid synthesis where the probe sequence is selected from a set of candidate sequences. McGall teaches optimizing array probe production based on results of testing conditions, such as by determining full length synthesis probability as discussed above. Therefore, both Tomiuk et al. and McGall teach optimizing techniques for producing microarrays and their combination made obvious the instantly claimed invention as stated in the instant office action.

Applicant's arguments, filed 3/31/2008, with respect to the rejection of claims 8-9 and 28-29 being rejected under 35 U.S.C. 103(a) as being unpatentable over McGall (US P/N 5,843,655) in view of Tomiuk et al. (December 2001) as applied to claim 1-7, 13-15, 22, 24-27, and 30-31 above, and further in view of Minor et al. (Pub No. US 2004/0019466) have been fully considered and are persuasive because of applicant's statement made under

103 (c) to disqualify the use of the Minor et al. reference as prior art. Therefore the rejection has been withdrawn.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform

with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Michael Borin, Ph.D./

Primary Examiner, Art Unit 1631